MAY 24 2005

K051040

(Optional Format 3-10-98)

510(k) Summary

Date Prepared: April 20, 2005

Submitter:
Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:
Bruce Backlund
Senior Regulatory Affairs Specialist

Phone: (763)-391-9183
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: Heparin Dose Response Control

Common Name: Analyzer, Heparin, Automated

Classification: Class II

Predicate Devices: Heparin Dose Response Controls K043080

Device Description

The HDR Control set is an *in vitro* diagnostic device. The primary function is to identify if each pair of heparinized channels of the HDR cartridge has normal or abnormal function by measuring if the clotting time ratios between heparinized and unheparinized channels are within or outside a specified range. HDR control 1 is used to verify that channels 1,2, 5 and 6 of the HDR cartridge are functioning correctly. HDR control 2 is used to verify that channels 3, 4, 5 and 6 of the HDR cartridge are functioning correctly.

The HDR controls are single use, non-sterile, point of care, *in-vitro* diagnostic plasma controls for use with the HMS *Plus* instrument.

Indication for Use

The Heparin Dose Response (HDR) controls are used to verify the performance of the HDR cartridges and the HMS Plus instrument.

Comparison to Predicate Device

The predicate device 510(k) K043080 was cleared on December 3, 2004.

Summary of Performance Data

Validation testing was used to establish the performance characteristic of the modifications of this device from the previously marketed device.

Conclusion

Medtronic Perfusion Systems has demonstrated that the HDR Controls are substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 4 2005

Mr. Bruce Backlund
Senior Regulatory Affairs Specialist
Medtronic Perfusion Systems
7611 Northland Drive
Brooklyn Park, MN 55428-1008

Re: k051040
Trade/Device Name: Heparin Dose Response Controls
Regulation Number: 21 CFR 864.5680
Regulation Name: Automated heparin analyzer
Regulatory Class: Class II
Product Code: JOX
Dated: April 20, 2005
Received: April 25, 2005

Dear Mr. Backlund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051040

Device Name: Heparin Dose Response Controls

Indications For Use:

The Heparin Dose Response (HDR) controls are used to verify the performance of HDR cartridges and the HMS Plus instrument.

Prescription Use ___X_____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Josephine Bautista

Division Sign-Off

Page _1_ of _1__

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051040